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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/836,636  | 04/17/2001  | Srikanth Venkatraman | IN01155K            | 7298             |
| 24265   | 7590        | 11/13/2003           | EXAMINER            |                  |
| SCHERING-PLOUGH CORPORATION<br>PATENT DEPARTMENT (K-6-1, 1990)<br>2000 GALLOPING HILL ROAD<br>KENILWORTH, NJ 07033-0530 |             |                      | LUKTON, DAVID       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1653                |                  |

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Applicati n No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/836,636             | VENKATRAMAN ET AL.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | David Lukton           | 1653                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22, 24-39 is/are pending in the application.
- 4a) Of the above claim(s) 24-25, 32, 33, 36, 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-31, 34, 35, 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1 and 21 is/are rejected.
- 7) ☒ Claim(s) 2-20, 22 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Pursuant to the directives of the amendment filed 10/6/03, claims 1-4, 28 have been amended. Claims 1-22, 24-39 remain pending. Claims 34, 35, 38, 39 are now rejoined with the elected group. Claims 24-25, 32, 33, 36, 37 remain withdrawn from consideration. Claims 1-22, 26-31, 34, 35, 38, 39 are examined in this Office action. Applicants' arguments filed 10/6/03 have been considered and found persuasive.

Claims 1 and 21 are now rejected over references not previously of record. Claims 2-20, 22, 26 are objected to because of their dependence on rejected claims. Claims 27-31, 34, 35, 38, 39 are characterized as allowable.

\*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Shimada (JP 7-228594).

Shimada discloses (col 13) compound 8 which is the following (wherein the *epsilon* amino group of lysine is bonded to the *beta*-carboxyl group of aspartic acid):

Lys-Val-Tyr-Phe-Asp-His-Leu-Asp-Ile-Ile-Trp

This is encompassed by instant claim 1 when the substituent variables correspond as follows:

R3 = benzyl

Z = N

R4 = H

W = >C=O

Y =  $\begin{array}{c} | \\ -\text{NH}-\text{CH}-\text{CH}_2-\text{C}_6\text{H}_4-\text{OH} \end{array}$

X = -NHCO-CH(NH<sub>2</sub>)-(CH<sub>2</sub>)<sub>4</sub>-

A = absent

E = alkylamide

G = -(CH<sub>2</sub>)<sub>p</sub>-

Q = N

V = CH

p = 0

R2 = imidazolylmethyl

R1 = -CO-NH-R<sup>10</sup>

NH-R<sup>10</sup> = Leu-Asp-Ile-Ile-Trp

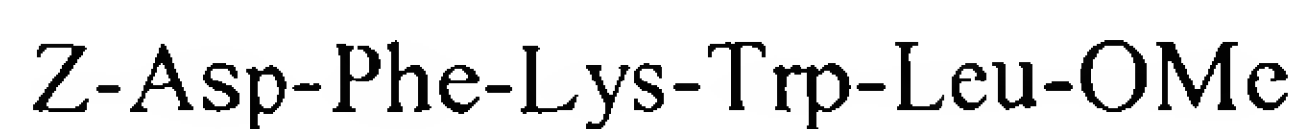
Thus, the claim is anticipated.

\*

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Dutta (*J. Med. Chem.*

33, 2552 1990).

Dutta discloses (p. 2553) compound 5 which is the following (wherein the *epsilon* amino group of lysine is bonded to the *beta*-carboxyl group of aspartic acid):



This is encompassed by instant claim 1 when the substituent variables correspond as follows:

R3 = benzyl

Z = N

R4 = hydrogen

W = >C=O

Y = C<sub>6</sub>H<sub>5</sub>-CH<sub>2</sub>-OCONH-CH-CH<sub>2</sub>-

X = absent

A = >C=O

E = -NH-(CH<sub>2</sub>)<sub>4</sub>-

G = -(CH<sub>2</sub>)<sub>p</sub>-

Q = N

V = CH

p = 0

R2 = indolylmethyl

R1 = -CO-NH-R<sup>10</sup>

NH-R<sup>10</sup> = Leu-OMe

Thus, the claim is anticipated.

\*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 21 is rejected under 35 U.S.C. §103 as being unpatentable over Dutta (*J. Med. Chem.* 33, 2552 1990).

A compound taught by Dutta is indicated above. Dutta also discloses that the compound inhibits renin. Dutta does not disclose combining the compound with a pharmaceutically acceptable carrier. However, drug formulation specialists of ordinary skill are acquainted with methods of preparing pharmaceutical formulations in which the carrier facilitates administration of a pharmacologically active compound in unit dosage form.

Thus, the claim is rendered obvious.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*D. Lukton* 11/10/03

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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